Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2101075	08/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Circulogene Theranostics	3125 Independence Dr Suite 301, Homewood, AL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A complaint survey was performed on August 26, 2021, based on a complaint intake (AL00039614) on 07/20/2020. The complaint included the following allegations: a) No maintenance procedures b) No Quality Control procedures c) No training policies d) No cleaning e) Cyber security issues f) No job descriptions g) No written procedures As a result of this complaint investigation, the following deficiencies were cited: a) The laboratory failed to verify the accuracy of test procedures when proficiency testing is unavailable (Refer to D5217). b) The laboratory's procedure manual failed to include a procedure describing its current practices of entering results and reporting patient results in 2020 to 2021 (Refer to D5403). c) The laboratory failed to perform maintenance on its instrumentation, according to the manufacturer's guidelines (Refer to D5429). d) The Laboratory Director failed to ensure his approval of the procedure manual, as would be evidenced by his signature (Refer to D5407). e) The Laboratory Director failed to ensure the laboratory was performing semi-annual and/or annual competency assessments for new testing personnel (Refer to D6107). .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of External Lab Cross Comparison records, Policy and Procedure Manual - Proficiency Testing, and an interview with the Technical Supervisor, the laboratory failed to verify the accuracy of test procedures when Proficiency Testing is unavailable. This was noted for 2021 for NTRK (Neurotrophic Tyrosine Receptor Kinase), PD-L1 (Programmed Death - Ligand 1), and ALK-ROS1 (Anaplastic lymphoma kinase c-ros oncogene 1). The findings include: 1. A review of External Lab Cross Comparison records revealed the following: a.) Proficiency, NTRK Gene Fusion Test i.) September 2020 - Three samples sent to Foundation Medicine for

	comparison. ii.) March 2020 - Three samples sent to Foundation Medicine for comparison. b.) ProGenetics, Proficiency, PD-L1 Test i.) September 2020 - Three samples sent to Liquid Genomics for comparison. ii.) March 2020 - Three samples sent to Liquid Genomics for comparison. iii.) October 2019 - Three samples sent to Liquid Genomics for comparison. iv.) April 2019 - Three samples sent to Liquid Genomics for comparison. c.) Proficiency, ALK-ROS1 Gene Fusion Test i.) September 2020 - Three samples sent to Biodesix for comparison. ii.) March 2020 - Three samples sent to Biodesix for comparison. iii.) November 2019 - Three samples sent to Biodesix for comparison. iv.) March 2019 - Three samples sent to Biodesix for comparison. d.) Promega, Proficiency, MSI Test - Moved to Proficiency Testing in November 2020. i.) March 2020 - Three samples sent to Thermo Fisher for comparison. ii.) December 2019 - Three samples sent to Thermo Fisher for comparison. iii.) April 2019 - Three samples sent to Thermo Fisher for comparison. 2. A review of Policy and Procedure Manual - Proficiency Testing (Doc #: QS - 076) revealed under 5.1.2 Proficiency Testing Unavailable " ...5.1.2.2 In the event a proficiency testing program is not available, CirculoGene will send specimens to an external lab for accuracy comparison purposes ..." 3. During an interview on 08/26 /2021 at 10:40 AM, the Technical Supervisor stated accuracy comparisons had not been performed in 2021.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of Policy and Procedure Manual and an interview with the Technical Supervisor, the laboratory's procedure manual failed to match the current method of entering results and reporting patient results in 2020 to 2021. The findings include: 1. A review of Policy and Procedure Manual revealed the procedures listed below did not mention the current method of Laboratory B (Dry Laboratory - professional component) location interpreting the results Laboratory A (Wet Laboratory - technical component). a.) Post-Analytical Documents (Doc#: PO - 25) b.) Post-Analytical Documents (Doc#: PO - 26) c.) Results Reporting (Doc #: PO - 27) d.) Microsatellite Instability (MSI) Test (SOP #: GN-004) e.) Cancer Mutation Panel Test by Next-Generation Sequencing (Laboratory Developed Test) (Doc#: GN -

	001) f.) NTRK Gene Fusion Test (Laboratory Developed Test) (Doc#: GN - 007) g.) Hereditary Cancer Panel Test by Next-Generation Sequencing (Laboratory Developed Test) (Doc#: GN - 005) h.) PD-L1 Gene Expression Test (Laboratory Developed Test) (Doc#: GN - 003) i.) ALK and ROS1 Gene Fusion Test (Laboratory Developed Test) (SOP#: GN - 002) 2. During an interview on 08/26/2021 at 11:48 AM, the Technical Supervisor confirmed they did not have a procedure that reflected the current practice of Laboratory B (Dry Laboratory - professional component) location interpreting the results for Laboratory A (Wet Laboratory - technical component).
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Technical SOP's (Standard Operation Procedures) and the General Policy and Procedures (P&P), and an interview with the Technical Supervisor, the surveyor determined the current Laboratory Director failed to sign and date the procedures to indicate his review/approval, upon assuming the directorship in April 2021. The findings include: 1. A review of the Technical SOP's and General P&P revealed no signature/date by the current Laboratory Director to indicate his review and approval of the procedures used by the testing personnel. 2. A review of a CMS-116 (CLIA Application for Certification) submitted by the laboratory in early 2021 revealed a request to change the Laboratory Director. This change was entered in ASPEN (a CMS database) on 4/21/2021 (four months before the current survey). 3. During a phone interview on 8/25/2021 at 9:48 AM, the Technical Supervisor confirmed the identity of the current Laboratory Director. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of 2019-2021 maintenance records and an interview with the Technical Supervisor, the laboratory failed to perform and document maintenance with the frequency specified by the manufacturer on QuantStudio 3, the QuantStudio 6, the SeqStudio, and Iron Chef. The findings include: 1. A review of laboratory records revealed missing documentation of August 2019 thru August 2021 maintenance on four instruments, as follows: A) QuantStudio 3 a) Weekly Maintenance: no documentation September 2019 b) Monthly maintenance: no documentation 7 of 24 months c) Semi-annual maintenance: no documentation second half of 2019 or in 2020 B) QuantStudio 6 a) Weekly Maintenance: missing documentation in October and November 2020 b) Monthly maintenance: no documentation in October, November and December 2020 c) Semi-annual maintenance: no documentation second half of 2019 C) SeqStudio a) Weekly Maintenance: no documentation October 2019 thru February 2020 b) Bi-weekly Maintenance: no documentation October 2019 c) Four-month Maintenance: no

	documentation the end of 2019 D) Iron Chef with missing Weekly Maintenance September 2019, April 2020 and December 2020 2. During an interview and review of the records on 8/26/2021 at 1:36 PM, the Technical Consultant confirmed the above noted findings. .
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on interview with technical supervisor and competency documentation record review the laboratory director failed to ensure that the laboratory was performing semi-annual and/or annual competency assessment for new testing personnel. Findings include: 1. Record review revealed the laboratory Technical Supervisor failed to perform semi-annual and/or annual competency assessment for 6 of 7 testing personnel hired between February 2020 and November 2020. The laboratory failed to perform semi-annual and/or annual competency assessment for Testing Personnel hired on the following dates: TP # 2- 2/10/2020 TP # 3- 6/08/2020 TP # 4- 7/20/2020 TP # 5- 8/17/2020 TP # 6- 11/16/2020 2. The laboratory Standard Operating Procedures states on page 2 of 4 "Competency Assessment" Competency of newly hired technical laboratory employees will be assessed six months after completion of initial training and annually thereafter. As of date of survey on August 26, 2021, TP#2 - 4 did not have a semi-annual or annual competency completed and TP#5 - 6 did not have a semi-annual completed. 3. The Technical Supervisor confirmed on August 26, 2021 at 10:00 am that the laboratory did not perform competency assessments as required for new TP hired in 2020.